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March 6, 2002

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United States Patent and Trademark Office
Attn: application number 09/736,351
Washington, DC 20231

Dear Sir,

I am resubmitting my rewritten patent application in response to the review I received,
(Art Unit: 2882). The review was done by Therese Barder.

My specific responses are:

1. References have been omitted as they did not contributed to the description of the process.
2. Same as one above.
3. Three figures have been added.
4. There is only one claim which is numbered.
5. There is only one claim.
6. The subject matter is described to sufficient detail to enable one skilled in the field of radiation therapy physics to make use of the invention. The subject matter of the claim is now spelled out in the claim.
7. The claims now define the invention.
8. The invention is original. See 9 below.
9. In regards to patent number 5,754,622 by John H. Hughes. This patent describes a process whereby the exit dose emerging from the patient is used to perform quality control whereas my process uses the entrance dose before the radiation beam reaches the patient. In the first place, I do not believe the process using the

*Please enter as Amendment A
Therese Barder*

exit dose can be made to work to sufficient accuracy to render the process of any use. A significant amount of radiation will scatter from the patient onto the exit imaging device. That scatter dose will have to be accounted for and removed from the signal, a difficult mathematical process. Then the rays must be back traced through the patient to arrive at the entrance field. I suspect the uncertainty at this point will be so large as to render the final result of not much use in determining if the patient is getting the correct dose. Measuring the entrance dose directly as opposed to deriving it from the exit dose is a significant difference. The entrance dose can be measured as accurately as any beam is now typically measured, yielding a resultant dose calculation that is as accurate as the original plan. Both processes then uses the entrance dose to compute the dose the patient receives. This is no different then employed by treatment planning systems which simulate the entrance dose. What is claimed is the process of using a measured entrance dose to perform quality control.

10. Although I can appreciate the need for a patent attorney, I cannot afford to use one and therefore am giving it my best shot.

Sincerely yours,

A handwritten signature in cursive script that reads "Wendel Dean Renner".

Wendel Dean Renner, President



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Title of Invention: Radiation Therapy Dosimetry Quality Control Process

Invented by:

Wendel Dean Renner, a citizen of the United States of America.
(A single individual working alone comprising a small entity.)

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Brief Summary of the Invention

The invention consists of a process for verifying the accuracy of the radiation dose delivered to patients undergoing external beam radiation therapy for the treatment of neoplastic disease. The process consists of measuring and calibrating an image of each radiation field that is to be applied to the patient. The measured field images are then used to compute the dose distribution to the patient using anatomical cross sectional images of the patients body and a dose algorithm. The resultant dose distributions are then available for comparison to the intended prescribed treatment plan.

Detailed Description

The process described below is for the purpose of verifying and testing the intended treatment plan to be applied to a patient using external beam radiation. It is assumed that a radiation therapy treatment plan has been developed employing current standard state of the art treatment planning techniques. These techniques generally involve obtaining cross sectional images of the patient's body with CT scanners or other means, and generating a treatment plan using computerized treatment planning systems provided for that purpose. CT is generally the imaging modality preferred due to its geometric accuracy and that CT pixel numbers can be converted to electron density needed by dose algorithms. MRI and mechanical means for obtaining cross sectional outlines are also sometimes employed.

Inherent in any activity carried out by human beings in particular is the possibility of errors. These errors may involve a misunderstanding between the physician prescribing the radiation dose and the technician who generally operates the treatment planning system to develop a plan. Individuals might make mistakes in the generation of the plan, such as setting the wrong distance for a field as one example. The development of the treatment plan might be a complex process involving devices placed in the beam to modify the radiation field, such as shielding blocks, wedges, compensating filters, and dynamic intensity modulation with multi-leaf collimators, to name a few common such devices (see Figure 1). Compensating filters are typically individually designed and manufactured for the particular field for a particular patient. Multiple fields are typically employed to converge upon a single contiguous treatment volume.

Any error in the weighting of these fields or in the modifying devices placed in the fields will lead to an error in the final result. We also must consider the nature of the radiation itself. Ionizing radiation cannot be seen, heard, felt, tasted, or smelled and so there is no sensual feedback to the operator of the treatment planning and delivery equipment. Radiation can only be measured with complex equipment by measuring the effects of the radiation, namely the ionization produced in air and other effects. Further, the delivery of

the treatment requires that the correct devices be placed in the beam in the intended correct position and that their effects are properly accounted for. This lengthy and complex process has multiple opportunities for errors to be committed by persons or machines. The standard state of the art procedures for quality control generally call for the checking of each component of the treatment planning and delivery process. It is assumed, and hoped, that when all the components are correct that the end result is correct. Yet without a feedback mechanism for the entire treatment planning and delivery process, failure to detect a problem with any component or underlying concept will most likely go unnoticed.

The only feedback mechanisms commonly employed consist of making a surface measurement on the patient's skin. This surface measurement can be related to a predicted dose value. However, the measurement at one or a few points does not demonstrate how the effects of all the treatment beams are adding up nor show the dose to the target volume or critical structures. Errors can still exist at other positions within the radiation field that will not be detected, such as the point measurement was performed on the central ray but the wedge was reversed in position. Making measurements inside the patient is generally limited to a few points if there is a cavity available and is an invasive procedure. Systems which intend to compute the dose distribution from measured exit dose have yet to demonstrate an accuracy to be of sufficient use.

The present invention consists of providing a more complete feedback mechanism whereby the dose to the patient volume can be assessed in 2d plane views and 3d perspective room views. The process begins with the measurement of each of the radiation fields that are to be applied to the patient as in Figure 1. Any suitable device may be used to measure the radiation field, such as x-ray film, a field imager consisting of a phosphor screen and video camera, or diode or ion chamber arrays. We will describe the process using x-ray film in ready pack, using either Kodak therapy verification film or more preferably a slower film such as Kodak EDR2 film in ready pack, and assume for here x-ray only treatments although the technique can be employed for electron therapy.

Electrons, however, do not present quite the same quality control problem as x-rays do as generally only one electron field irradiates a target volume at a fixed distance and the dose delivered is closely related to the monitor units applied.

An image of each field is made in a plane perpendicular to the central axis of the beam at a known distance from the x-ray source down stream from all the in beam modifiers (see Figure 1). This image may be taken during a dry run without the presence of the patient, or may be taken during treatment if the patient can be treated through the imaging device (as in Figure 2). The image is of the radiation field before it reaches the patient. There has to be sufficient buildup material (bolus) above the film or device used to capture the image to shield the image receptor from contamination electrons which would otherwise fog the image. For example, 1.5 cm water equivalent material is needed for 6 MeV x-rays, 3.5 cm water equivalent material for 18 MeV x-rays. Some material of the order of 1 cm or less might be required under the imaging surface to protect from back scattered contamination electrons, depending upon the equipment and surfaces employed, but a phantom with full backscatter is not to be employed under the imaging surface. Electron beams would not require buildup material. The captured field image is to approximate the in air fluence of energy emerging from the radiation source. The use of bolus (buildup) above the image receptor with x-rays to shield out contamination electrons will not significantly degrade the measured distribution of the in air fluence, but effects of the buildup can also be removed as described below. The measuring device may be placed upon the treatment couch or may be attached to the collimator of the treatment machine.

To remove the effects of buildup, the measured image can be processed with a high band pass spatial filter. The scatter generated by the buildup will act like a low pass spatial filter and high frequency information attenuated but not lost can be restored in this process.

If the shape of the beam is changing while the gantry rotates or is modulated during gantry rotation or any other movement changes the beam's position while the beam is modified in

shape or cross sectional intensity, then images of the field must be made in sequence so that such a sequence of discrete measured beams can approximate the continuous motion employed. This can be accomplished with suitable equipment, such as a field imager with a tilt indicator for the case when only the gantry is rotating.

The response of the measuring device must be corrected for and calibrated in terms of the monitor units applied on the treatment machine. To run a calibration curve, a 10x10 cm field should be set (that is, the field size at which the scatter collimator factor is typically normalized to and the field size that the calibration of the treatment machine is usually specified at), and exposures made for different monitor units covering the treatment range but possibly limited by the dynamic range of the imaging device. A software system provided for this application running on a computer generates a curve relating monitor units as the dependent variable to the pixel value at the center of this calibration field as the independent variable. This curve is then applied to each of the measured treatment fields to convert the pixel values covering the area of the measured field to monitor units. These monitor units are referred to as relative monitor units. Allowance is made in the software system provided for this application for measuring the field images at different distances by applying an inverse square law correction. The user must know or determine the distance to the image in all cases and must know the orientation of the image relative to the collimator of the treatment machine. If the dynamic range of the imaging device does not allow the full treatment, then either multiple images are to be taken and added together, or a single image may be scaled by the ratio of the monitor units used to make the image to the monitor units intended for the field. The latter assumes that the field does not change during the delivery of the entire monitor unit prescription. The software provides tools for locating the central ray of the radiation beam if at least two orthogonal edges of the field defined by the collimator are visible. Otherwise external fiducial marks must be relied upon or there must be a positive lock between the imaging device and the collimator so that the position of the central ray is always known as well as the orientation and rotation of the field image relative to the collimator. External fiducial marks would consist of small marks whose position is known relative to the beam's central ray. With

film in ready pack, one can simply use a pin to make marks on the film on the x and y axes of the radiation field as identified by the beam's light field.

For an example of the meaning of relative monitor units, if the scatter collimator factor for a 40x40 field cm is 1.05 relative to 1.0 for a 10x10 cm field and a 100 monitor unit exposure is made, then the center of the 40x40 field has a relative monitor unit value of $1.05 \times 100 = 105$ relative monitor units. In air off axis effects will change the relative monitor unit at other positions in the image plane, as will the application of devices such as shielding blocks, compensators, and wedges.

Another issue that must be considered is variation of the imaging device response over time, such as variation in film processing, that will change the dose response curve. We have three means of correcting for that. One is to generate a new calibration curve each time the system is used. This is expedited by providing a means to calibrate a step wedge once and then using an image of the step wedge made with each set of field images. A calibration curve is generated from the image of the step wedge. A second method that is provided is to renormalize the field after conversion to relative monitor units to that at a single point measured within the field. Here a parallel plate ion chamber (or cylindrical) or a diode is employed in the bolus stack immediately above or below the imaging surface. This device is also to be calibrated in terms of monitor units identically to how the imaging device is calibrated. The field image is then normalized at the point of measurement. This will require that the position of the measurement be known within the field image and that the measuring device not significantly affect the recorded image of the radiation field. A third means is to make one additional calibration film at the time the beam fields are imaged and use the known single point to rescale the prior calibration curve.

The field images must be converted to digital form. If using film, the processed films must be digitized and converted to TIFF, PNG, or DICOM format. The software system developed here reads in these field images in digital form and converts the pixel values to relative monitor units. The software system then reads in the CT scans or other cross

sectional images that were used in the treatment planning process. The position of the isocenter of each treatment field is determined from the specification in the treatment plan. Likewise the couch, gantry, and collimator angles are specified. Each beam is then associated with the above field image calibrated in terms of relative monitor units.

A dose algorithm provided in the software system then computes the dose distribution to the patient in the same manner that a treatment planning system does except that the input and specification for the fluence for each field comes from the above measured field beam images calibrated in terms of relative monitor units and not from a model of the beam and inserted devices. The dose distribution may then be plotted on two dimensional cross sectional images through the patient image set, in transverse, coronal, sagittal, or other planes, but generally in planes identical to the planes plotted with the planning system (see Figure 3). The dose result is then to be directly compared to the prescription and treatment plan. The dose may also be display in perspective room views along with the anatomy and outlined regions of interest. Lastly, dose difference plots and histograms may be produced if the dose distribution from the planning system is available (Figure 3).

The particulars of the dose algorithm employed are not important here but any algorithm used must be capable of using a measured field fluence derived from dose to compute the dose. We are using a pencil beam algorithm. Although the field fluence is calibrated in terms of monitor units, what is actually measured at the image plane is dose. Each radiation field is divided into small subunits which are commonly referred to as pencil beams. Relative monitor units are then used to normalize the weight of these small subunits of the applied field. The dose to the patient is then computed from the sum of the dose contribution from all such subunits that make up the applied radiation field and this part of the algorithm is no different from that typically employed by treatment planning systems.

The result provides a dose distribution computed from the measured fields (Figure 3). Any significant error in the prescribed monitor units, field size, or applied devices within

the field will be evident as the dose distribution computed here will disagree with the intended plan. We have here provided a feed back mechanism for verifying the patient dose.

False negatives may be possible due to common errors in both this verification system described here and the treatment planning and delivery system, but we have significantly reduced the number of common variables. Any significant difference between this verification computed dose and the plan dose should be investigated and resolved before the patient is treated. The opportunity therefore exist to resolve any false positive result that might occur.

It will be equally important for the user to understand the parameters that are not verified with this system. The system might not be very sensitive to selecting the wrong energy for the beam. Nothing is done to verify that the treatment fields are in fact properly placed on the patient. Here we are only checking the dosimetry of the plan and the effects of the devices used within the beam.